

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Steven B. Landau, Cheryl L. Miller and Karl B. Thor  
Application No.: 10/757,981 Group Art Unit: Unknown  
Filed: January 13, 2004 Examiner: Unknown  
Confirmation No.: Unknown  
Title: METHOD OF TREATING NAUSEA, VOMITING, RETCHING OR ANY  
COMBINATION THEREOF

CERTIFICATE OF MAILING OR TRANSMISSION	
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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:  
☐ a Statement under 37 CFR 1.97(e), as checked below, or  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:  
☐ a Statement under 37 CFR 1.97(e), as checked below, and  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
  - ☒ Copies of the cited references are enclosed.
    - ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
  - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
  - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
  - ☒ The "concise explanation" requirement (non-English references) for references AL and AQ under 37 CFR 1.98(a)(3) is satisfied by:
    - ☐ the explanation provided on the attached sheet.
    - ☐ the explanation provided in the Specification.
    - ☐ submission of the enclosed International Search Report.
    - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
  - ☒ the enclosed English language abstracts.

[X] Applicants requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_\_ U.S. Patent Application No. 10/757,364, by Steven B. Landau, filed January 13, 2004,  
Docket No.: 3506.1000-002

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

[X] A copy of each above-cited application, including the current claims, is enclosed.

[ ] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Remarks

References AW4 and AX4 are copies of the British priority documents for International Application No. PCT/GB2003/002974 (WO 2004/004734 A1, published on January 15, 2004, Reference AL2). Copies of priority documents for international applications filed under the Patent Cooperation Treaty are available through WIPO upon publication of the international application pursuant to Rule 17.2(c) PCT. Copies of References AW4 and AX4 were obtained in this manner.

Method of payment:

[ ] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

[ ] Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.

[X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated:

March 1, 2004

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.  
3506.1001-002APPLICATION NO.  
10/757,981INFORMATION DISCLOSURE CITATION  
IN AN APPLICATIONFIRST NAMED INVENTOR  
Steven B. LandauFILING DATE  
January 13, 2004

March 1, 2004

EXAMINER  
UnknownCONFIRMATION NO.  
UnknownGROUP  
Unknown

(Use several sheets if necessary)

## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	6,054,461	04-25-2000	Fairbanks <i>et al.</i>
	AB	6,117,879	09-12-2000	Fairbanks <i>et al.</i>
	AC	6,441,038 B1	08-27-2002	Loder <i>et al.</i>
	AD	6,376,550 B1	04-23-2002	Raber <i>et al.</i>
	AE	6,156,771	12-05-2000	Rubin <i>et al.</i>
	AF	6,552,045 B2	04-22-2003	Sepracor Inc.
	AG	4,783,478	11-08-1988	Wootton <i>et al.</i>
	AH	6,465,458 B1	10-15-2002	Wong <i>et al.</i>
	AI	4,695,568	09-22-1987	Ninomiya <i>et al.</i>
	AJ	2002/0107244 A1	08-08-2002	Howard, Jr.
	AK	6,355,647 B1	03-12-2002	Steiner <i>et al.</i>
	AA2	5,990,159	11-23-1999	Meulemans <i>et al.</i>
	AB2	5,962,494	10-05-1999	Young
	AC2	5,945,415	08-31-1999	Kato <i>et al.</i>
	AD2	5,663,343	09-02-1997	van der Meij <i>et al.</i>
	AE2	5,576,317	11-19-1996	Gonsalves
	AF2	5,470,868	11-28-1995	Young
	AG2	5,352,685	10-04-1994	Maruyama <i>et al.</i>
	AH2	5,225,407	07-06-1993	Oakley <i>et al.</i>
	AI2	4,939,136	07-03-1990	Haeck <i>et al.</i>
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	AK2	2001/0020025 A1	09-06-2001	Megens
	AA3	2002/0002197 A1	01-03-2002	Mueller <i>et al.</i>
	AB3	2002/0086880 A1	07-04-2002	Rubin <i>et al.</i>
	AC3	2002/0086881 A1	07-04-2002	Rubin <i>et al.</i>
	AD3	4,753,789	06-28-1988	Tyers <i>et al.</i>

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <b>March 1, 2004</b>  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3506.1001-002		APPLICATION NO. 10/757,981	
	FIRST NAMED INVENTOR Steven B. Landau		FILING DATE January 13, 2004	
	EXAMINER Unknown	CONFIRMATION NO. Unknown	GROUP Unknown	

U.S. PATENT DOCUMENTS				
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AE3	2003/0203055 A1	10-30-2003	Rao <i>et al.</i>
	AF3	5,985,866	11-16-1999	Müller <i>et al.</i>
	AG3	5,977,127	11-02-1999	Bonnacker <i>et al.</i>
	AH3	5,530,008	06-25-1996	Azcona <i>et al.</i>
	AI3	4,845,092	07-04-1989	Sanger <i>et al.</i>
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	AB3	6,593,336 B2	07-15-2003	Mangel <i>et al.</i>
	AC3	2003/0036549 A1	02-20-2003	Mangel <i>et al.</i>
	AD3	2003/0036500A1	02-20-2003	Rubin <i>et al.</i>

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	EXAMINER Unknown		CONFIRMATION NO. Unknown	GROUP Unknown

FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	AL +	WO 99/02516	01-25-1999	Vita-Invest, S.A.		X
	AM +	WO 02/44170 A2	06-06-2002	Vita-Invest, S.A.		
	AN +	WO 02/094249 A1	11-28-2002	Arachnova Therapeutics Ltd.		
	AO +	WO 03/077897 A1	09-25-2003	Cypress Bioscience, Inc.		
	AP +	WO 94/01095 A3	01-20-1994	Smith-Kline Beecham PLC		
	AQ +	WO98/50037	11-12-1998	Mitsubishi Chemical Corporation		X
	AL2 +	WO 2004/004734 A1	01-15-2004	Arachnova Therapeutics Ltd.		
	AM2 +	WO 01/41748 A2	06-14-2001	Novartis AG		
	AN2 +	WO 00/51583 A3	09-08-2000	Sepracor, Inc.		
	AO2 +	WO 00/51584 A3	09-08-2000	Sepracor, Inc.		
	AP2 +	EP 0 313 393 B1	03-16-1994	Yoshitomi Pharmaceutical Industries, Ltd.		

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	EXAMINER Unknown		CONFIRMATION NO. Unknown	GROUP Unknown

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AR	✓	Milano, S, <i>et al.</i> , "The Piglet as a Suitable Animal Model for Studying the Delayed Phase of Cisplatin-Induced Emesis," <i>J. Pharmacol. Exp. Ther.</i> , 274(2): 951-961 (1995).
AS	✓	Prakash, C., <i>et al.</i> , "Tricyclic Antidepressants for Functional Nausea and Vomiting: Clinical Outcome in 37 Patients," <i>Dig. Dis. Sci.</i> , 43(9):1951-1956 (1998).
AT	✓	Center for Drug Evaluation and Research Application Number: 020623; Pharmacology Reviews; July 5, 1996.
AU	✓	Angel, I., <i>et al.</i> "Litoxetine: A Selective 5-HT Uptake Inhibitor with Concomitant 5-HT <sub>3</sub> Receptor Antagonist and Antiemetic Properties," <i>Eur. J. Pharmacol.</i> , 232(2-3):139-145 (1993).
AV	✓	Crow, M.K., <i>et al.</i> "Management of Nausea and Vomiting," <i>Medical Oncology: A Comprehensive Review</i> , [Retrieved January 29, 2003] Retrieved from the Internet <URL:http://www.cancernetwork.com/textbook/morev41.htm>.
AW	✓	Depoortere, I., <i>et al.</i> , "Dose-Dependent Effects of Recombinant Human Interleukin-11 on Contractile Properties in Rabbit 2,4,6-Trinitrobenzene Sulfonic Acid Colitis <sup>1</sup> ," <i>J. Pharmacol. Exp. Ther.</i> , 294(3): 983-990 (2000).
AX	✓	Eguchi, J., <i>et al.</i> , "The Anxiolytic-Like Effect of MCI-225, A Selective NA Reuptake Inhibitor with 5-HT <sub>3</sub> Receptor Antagonism," <i>Pharm. Biochem. and Behavior</i> , 68:677-683 (2001).
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AR2	✓	Kuver, R., <i>et al.</i> , "Nausea and Vomiting in Adolescents and Adults," <i>Nausea and Vomiting</i> , [Retrieved January 29, 2003] Retrieved from the Internet <URL:http://www.uwgi.org/cme/cmeCourseCD/ch_01/ch01txt.htm>
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AT2	✓	Million, M., <i>et al.</i> , "Susceptibility of Lewis and Fischer Rats to Stress-induced Worsening of TNB-colitis: Protective Role of Brain CRF," <i>Amer. Phys. Soc.</i> , 276 (4 Pt 1): G1027-G1036 (1999).

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	EXAMINER Unknown	CONFIRMATION NO. Unknown	GROUP Unknown

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AU2 ✓	Prakash, C. and Clouse, R.E., "Cyclic Vomiting Syndrome in Adults: Clinical Features and Response to Tricyclic Antidepressants," <i>Am. J. Gastroenterol.</i> , 94(10): 2855-2860 (1999).	
AV2 ✓	Spiller, R., " Pharmacotherapy: Non-serotonergic Mechanisms" <i>Gut</i> , 51 (Suppl1): i87-90 (2002).	
AW2 ✓	Venkova, K., <i>et al.</i> , "Peripheral Activity of a New NK <sub>1</sub> Receptor Antagonist TAK-637 in the Gastrointestinal Tract," <i>J. Pharmacol. Exp. Ther.</i> , 300(3): 1046-1052 (2002).	
AX2 ✓	Wood, J.D., <i>et al.</i> "Fundamentals of Neurogastroenterology," <i>Gut</i> 45(2):II6-II16 (1999).	
AY2 ✓	Butler, A., <i>et al.</i> , "Pharmacological Properties of GR38032F, a Novel Antagonist at 5-HT <sub>3</sub> Receptors," <i>Br. J. Pharmacol.</i> , 94(2): 397-412 (1988).	
AR3 ✓	Sallan, S.E., <i>et al.</i> , "Antiemetics in Patients Receiving Chemotherapy for Cancer," <i>N. Eng. J. Med.</i> , 302(3): 135-138 (1980).	
AS3 ✓	Veyrat-Follet, C., <i>et al.</i> , "Physiology of Chemotherapy-Induced Emesis and Antiemetic Therapy," <i>Drugs</i> 53(2): 206-234 (1997).	
AT3 ✓	Morrow, G.R., <i>et al.</i> , "Progress in Reducing Nausea and Emesis," <i>Cancer</i> 76(3): 343-357 (1995).	
AU3 ✓	Eguchi, J., <i>et al.</i> , "Pharmacological Profile of the Novel Antidepressant 4-(2-Fluorophenyl)-6-Methyl-2-(1-Piperazinyl)thieno-[2,3-d]pyrimidine Monohydrate Hyrdocloride," <i>Arzneim.-Forschung/Drug Res.</i> , 47(12): 1337-1347 (1997).	
AV3 ✓	Kilpatrick, G., <i>et al.</i> , "Identification and Distribution of 5-HT <sub>3</sub> Receptors in Rat Brain Using Radioligand Binding," <i>Nature</i> , 330: 746-748 (1987).	
AW3 ✓	Ito, C., <i>et al.</i> , "Effect of GK-128 [2-[(2-Methylimidazol-1-yl)- benzo[f]thiochromen-1-one Monohydrochloride Hemihydrate], a Selective 5-Hydroxytryptamine <sub>3</sub> Receptor Antagonist, on Colonic Function in Rats," <i>J. Pharmacol. Exp. Ther.</i> , 280(1): 67-72 (1997).	
AX3 ✓	Owens, M. J., <i>et al.</i> , "Neurotransmitter Receptor and Transporter Binding Profile of Antidepressants and their Metabolites <sup>1</sup> ," <i>J. Pharmacol. Exp. Ther.</i> , 283(3): 1305-1322 (1997).	
AY3 ✓	Béïque, J.C., <i>et al.</i> , "Affinities of Venlafaxine and Various Reuptake Inhibitors for the Serotonin and Norepinephrine Transporters," <i>Eur. J. Pharmacol.</i> , 349(1): 129-132 (1998).	

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	EXAMINER Unknown	CONFIRMATION NO. Unknown	GROUP Unknown	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AZ3 ✓		Camilleri, M., "Serotonergic Modulation of Visceral Sensation: Lower Gut," <i>Gut</i> 51(1):81-86 (2002).
AR4		Burns, M.J., "The Pharmacology and Toxicology of Reboxetine," <i>Int. J. Med. Toxicol.</i> 3(4):26 1-8 (2000).
AS4 ✓		Bymaster, F.P., <i>et al.</i> , "Comparative Affinity of Duloxetine and Venlafaxine for Serotonin and Norepinephrine Transporters <i>In Vitro</i> and <i>In Vivo</i> , Human Serotonin Receptor Subtypes, and Other Neuronal Receptors," <i>Neuropsychopharmacology</i> , 25(6):871-880 (2001).
AT4 ✓		Wong, E.H.F., <i>et al.</i> , "Reboxetine: A Pharmacologically Potent, Selective, and Specific Norepinephrine Reuptake Inhibitor," <i>Biol. Psychiatry</i> . 47(9): 818-829 (2000).
AU4 ✓		LOTIRONEX - Tablets, <i>Product Information</i> , GlaxoSmithKline, Research Triangle Park, NC, pp. 1-13 (2002).
AV4 ✓		U.S. Provisional Application No. 60/364,531, filed 03-15-2002, entitled "Methods of Treating Visceral Pain Syndromes," by Rao <i>et al.</i> , priority document for WO 03/077897 A1 (Reference AO) and U.S. 2003/0203055 A1 (Reference AE3).
AW4 ✓		GB 0304648.9, filed 02-28-2003, entitled "New Therapeutic Use of 4-(2-Fluorophenyl)-6-Methyl-2-(1-Piperziny) Thieno[2,3-D] Pyrimidine," priority document for WO 2004/004734 A1 (Reference AL2).
AX4 ✓		GB 0216027.3, filed July 10, 2002, entitled "New Therapeutic Use," priority document for WO 2004/004734 A1 (Reference AL2).

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